REMARKS

Claims 21-23 and 25-48 and 50-53 are pending with claims 21, 36, 39, and 47 being independent. Claims 24 and 49 have been cancelled. Claims 21, 27, 36, 39, and 47 have been amended. The amendments to the claims find support in the claims and application as filed. For example, support for the biocompatible superelastic/shape memory material is found in the application as filed at page 27, lines 26-30 and Figures 76a and 76b. The amendment to recite compressing in place of reinforcing finds support throughout the application as filed. Newly added claims 52 and 53 find support in claims 29 and 30 as filed.

The Office Action requests new corrected drawings because the drawings have hand drawn portions. Applicants respectfully note that hand drawn drawings typically are acceptable if all other drawing requirements are met and thus request that the Examiner point to those particular drawings that must be replaced to meet the PTO's drawing requirements.

The Office Action requests that the abstract be corrected to have a length that is within the range of 50 to 150 words. Applicants have amended the abstract to have a word count of approximately 141 words and submit that this objection has been adequately addressed.

Claims 21-23, 27-30 and 34-36 have been rejected as being anticipated by Schmitt (US 6,375,662). As amended, claim 21 is directed to a medical device for placing against a tissue surface within a mammalian to close an opening in the tissue. The device includes at least one layer of a biocompatible material and at least one layer of a biocompatible superelastic/shape memory material. The biocompatible superelastic/shape memory material is in the form of a sheet having an upper side and a lower side and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material without the use of an adherent material. The biocompatible superelastic/shape memory material is configured to have a curved configuration in an unconstrained shape if the biocompatible superelastic/shape memory material is configured to have a superelastic property or to have a curved configuration in a heated, transformed shape if the biocompatible superelastic/shape memory material is configured to have a shape memory property.

Schmitt is directed to woven patches that are placed against soft tissue while also being configured to provide increased resistance to bacterial infections that can occur in the interstices between fibers in the woven patch. Schmitt accomplishes this increased resistance by coating the fibers or filling the interstices with a polymer resin. See e.g., Fig. 2a. Schmitt notes that the patches can have a shape imparted by heating or using nitinol threads. See column 8, lines 19-34 ("The mesh could also include individual threads having a shape-memory imparted thereto, such as nitinol threads.").

Schmitt, however, fails to describe or suggest the medical device of claim 21 having a sheet of a superelastic/shape memory material having an upper side and a lower side and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material without the use of an adherent material. First, Schmitt discloses using nitinol threads in his weave rather than a nitinol sheet. Nitinol threads and sheets differ from each other on a number of grounds. For example, threads are round while sheets are flat and threads may be flexible in all directions while sheets have limited degrees of flexibility. These differences in characteristics make a sheet of nitinol an unsuitable substitute for the nitinol threads in Schmitt's application because, as discussed below, Schmitt describes the pliability of the threads as being an advantage over a more rigid monofilament design.

Second, one of ordinary skill in the art reading Schmitt would not have been motivated to modify his threads to form a sheet. Schmitt is focused on solving the problem of infections resulting from using woven yarns where infectious agents can reside in the interstitial space between the filaments making up the yarn. See Figure 2a, reference numeral 27; column 1, lines 35-43:

> However, mesh formed of multifilament yarn may tend to harbor infectious matter such as bacteria. Particularly, the small void areas or interstitial spaces between the filaments of a multifilament yarn may promote the breeding of such bacteria. To date, surgeons typically prefer the monofilament design because of its improved resistance to harboring of infectious matter. As a result of this choice, surgeons must forego the advantages associated with multifilament yarns.

Schmitt solves this in one approach by surrounding the mass of fibers with the resin while leaving unfilled the interstitial voids within the fibers. See Figure 3, reference numeral 32.

Schmitt solves this in another approach by filling the interstitial spaces between the fibers with a resin. See Figure 4, reference numeral 36. A sheet of a material, whether it be nitinol or other superelastic/shape memory material, would not have been expected to have the infectious concerns addressed by Schmitt because there are no filaments in which voids can be formed.

Third, claim 21 recites the polymer covering portions of the superelastic/shape memory material without the use of an adherent material. In contrast, Schmitt uses resins that appear to adhere to the filaments. For example, Schmitt discloses polymer resins that are applied to the trellis of yarn as a hot melt (column 5, lines 37-47), as a resin solution in a solvent that is evaporated off (column 5, lines 48-51), and as a sheath around the fibers such that trellis can be heated to fuse the resin-based sheaths together (column 6, lines 7-21 and 27-38). Thus, Schmitt appears to be using adherent materials for his resin to fill the interstitial spaces between the fibers.

Finally, Schmitt teaches away from using a sheet of a material in place of his multifilament yarn by noting that surgical meshes made with a monofilament rather than a multifilament design are less advantageous because they do not have the advantages of softness and pliability that result in better assimilation of the mesh into the body:

> Surgical mesh is, of course, thoroughly sterilized prior to implantation. Nevertheless, surgeons typically prefer the use of monofilament-designed mesh to minimize any risk of infection. As a result the advantages associated with multifilament-designed mesh (i.e., softness and pliability which result in better assimilation of the mesh into the body) are typically sacrificed.
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> It has been discovered herein that a surgical support mesh having both the softness and pliability of a multifilament-designed mesh and the infection resistance of a monofilament-designed mesh may be produced. Particularly, it has been discovered that a support trellis formed of multifilament yarn wherein the interstitial voids located between adjacent filaments are enclosed within an infection-impervious matrix exhibits the desired resistance to harboring of infectious matter without significant loss of flexibility.

See column 4, lines 40-55 (emphasis added). Applicants submit that the pliability of a sheet is more similar to that of a monofilament than to a multiflament material. Thus, one of ordinary

skill in the art reading Schmitt would have been taught away from using the sheet of claim 21 in place of the threads of Schmitt.

For at least these reasons, claim 21 and dependent claims 22, 23, 27-30, 34 and 35 are allowable over Schmitt.

Independent claim 36 also has been rejected as being anticipated by Schmitt. Like claim 21, claim 36 recites a medical device having a sheet of a superelastic/shape memory material having an upper side and a lower side and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material without the use of an adherent material. Thus, for the same reasons that claim 21 is allowable over Schmitt, claim 36 is allowable over Schmitt.

Claims 25, 26, 31-33, 37-41, 43-48, 50 and 51 are rejected as being obvious over Schmitt in view of one or more of King (US 3,874,388), Forber (US 5,733,294), Zhu (US 6,589,269), Evard (US 5,536,251) and Hammerslag (US 5,653, 730).

King is directed to umbrella-like devices that are implanted through a catheter to close an opening in the cardiovascular system, such as a ventricular septal defect or a patent ductus arteriosus. The device includes a pair of umbrella-like portions that expand once outside of the catheter. Much like the configuration of an umbrella, the umbrella-like portions of the disclosed device include struts and a fabric that is tied to the struts (reference numerals 81, 91). See Figs. 1c and 4. The struts are described as being made of a radiopaque material but not necessarily being metal. However, King fails to cure the deficiency of Schmitt to describe or suggest a medical device having a sheet of a superelastic/shape memory material having an upper side and a lower side and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material. In particular, King does not disclose a sheet of superelastic/shape memory material but instead discloses what appears to be rod to form the struts. See Figure 2A. Moreover, King does not describe or suggest the fabric covering at least a portion of both the upper side and the lower side of the strut. Instead, it appears that the fabric is tied to the struts such that only a single side of the strut is covered.

Forber is directed to self-expanding cardiovascular occlusion devices used to occlude vessels and aneurysms. The devices are self-expanding and include a predetermined pattern of wire and collinear bands encircling the wire such that pushing the bands together causes two exposed braided or helical sections between them to flatten out for delivery through a catheter. After being released from the catheter, the device expands to fill an area of the vasculature, causes a clot to form, and ultimately results in an occlusion. The materials disclosed for making the wires includes superelastic materials such as nitinol. Forber states that filaments also can be positioned to extend from the bands. However, Forber fails to cure the deficiency of Schmitt to describe or suggest a medical device having a sheet of a superelastic/shape memory material having an upper side and a lower side and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material. First, Forber's only discloses of superelastic materials relates to its use in the wires. Like Schmitt, Forber does not disclose a sheet of a superlelastic/shape memory material. In addition, Forber does not disclose the wires having an upper side and a lower side being covered over at least a portion of the upper side and at least a portion of the lower side by the filaments.

Zhu discloses a patch and glue delivery system for applying a patch to close a tissue opening. The description of the patch is limited to a brief listing of its materials:

> The patch 60 is adapted to cover an opening in body tissue and may be shaped in any desired geometry and formed from any suitable patch material, such as PTFE, biovascular material, collagen, Gore-Tex®., Dacron®, etc. The patch may also be formed out of materials that will dissolve over time within the patient's body.

Thus, Zhu's patch cannot be characterized as having a superelastic/shape memory material much less a sheet of a superelastic/shape memory material. As such, Zhu fails to cure the deficiency of Schmitt to describe or suggest a medical device having a sheet of a superelastic/shape memory material having an upper side and a lower side and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material.

Evard is directed to surgical instruments for minimally invasive cardiovascular surgery and references surgical staples and a patch for closing openings in tissue. Evard's patch is not described beyond noting that it can be used to close a penetration in the wall of the aorta where a delivery catheter had been placed. See column 3, line 66 through column 4, line 3. Thus, Evard

fails to cure the deficiency of Schmitt to describe or suggest a medical device having a sheet of a superelastic/shape memory material having an upper side and a lower side and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material.

Hammerslag is directed to methods of applying adhesives to seal openings in tissue and discloses the use of porous polymer patches with the tissue adhesive:

> Tissue adhesives of the type described above are well suited to seal a typical PTCA arterial perforation, which commonly has a non-dilated diameter of about 1 mm, where the arterial wall is relatively elastic. However, where the arterial wall is relatively inelastic, and the typical PTCA arterial perforation commonly has a non-dilated diameter of about 2-3 mm, it has been found desirable to use a porous patch 150 in combination with the tissue adhesive to further improve the integrity of the seal across the arterial perforation.
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> [. . .]
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> The patch 150 is preferably formed of a mesh, weave or knitted material which is biocompatible, and preferably is biodegradable (i.e., is absorbable within the body). The patch 150 can be formed of any of a wide variety of suitable materials, such as, for example, polytetrafluoroethylene (PTFE), oxidized regenerated cellulose, Gelfilm™ available from the Upjohn Co. and collagen. A suitable material from which to form the patch 150 is a sterile absorbable mesh material (either knitted or woven) available commercially as VICRYL™ from Ethicon (a Johnson and Johnson company) of Somerville, N. J.
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> The patch 150 may be impregnated, coated, or otherwise pretreated at the point of manufacture with a tissue adhesive, such as, for example, any of the tissue adhesive types described above. In this manner, the adhesive coated surface of the patch 150 will adhere to the surface of the vessel surrounding the perforation upon application of the patch 150. Alternatively, the patch 150 and the tissue adhesive can be provided separately, and the patch 150 is saturated or coated with tissue adhesive at the time of application or just before application, as discussed below.

See column 11, lines 8-65. Hammerslag , however, does not describe or suggest that his patch may include a sheet of a supereleastic/shape memory material much less a medical device having a sheet of a superelastic/shape memory material having an upper side and a lower side and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material without the use of an adherent material.

Claims 25, 26, 31-33, 37-41 and 43-51 are allowable over Schmitt in view of one or more of King, Forber, Zhu, Evard or Hammerslag, taken individually or in combination, because they fail to cure the deficiency of Schmitt to describe or suggest a medical device having a sheet of a superelastic/shape memory material having an upper side and a lower side and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material without the use of an adherent material.

Claims 21-23, 25-28, 31-33 and 36-44 are rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-7, 9-16, and 18-20 of US 6,726,696. These claims are presented below:

1. A patch for placing against a tissue within a mammalian, the patch comprising: at least one layer of a biocompatible polymer; at least one layer of a biocompatible superelastic/shape memory material; and at least one layer of a biocompatible adherent material.

2. The patch of claim 1, wherein the superelastic/shape memory material comprises a nickel titanium alloy.

3. The patch of claim 2, wherein the alloy comprises Nitinol.

4. The patch of claim 1, wherein the superelastic/shape memory material has a curved configuration in a resting state.

5. The patch of claim 1, further comprising barbs extending from the superelastic/shape memory material.

6. The patch of claim 5, further comprising a power source connected to the patch and configured to provide power to the barbs.

7. The patch of claim 1, wherein the layer of superelastic/shape memory material is encapsulated by the polymer.

9. The patch of claim 1, wherein the patch comprises multiple arms and a base configured to form a concave shape.

10. The patch of claim 9, further comprising one or more barbs extending from the arms.

11. The patch of claim 1, further comprising a deployment device configured to deploy the patch, the deployment device comprising a handle and a deployment section, the deployment section configured to retain the patch for delivery of the patch to the vessel.

12. The patch of claim 11, wherein the deployment section includes a pair of openable jaws.

13. The patch of claim 11, wherein the deployment section includes a surface configured to apply a vacuum.

14. A method of applying a patch to a tissue surface within a mammalian body, the method comprising: retaining the patch to a deployment device; advancing the deployment device to the tissue surface; pressing the patch against the tissue surface; and manipulating the deployment device to separate the deployment device from the patch and leave the patch against the tissue surface, wherein the patch comprises at least one layer of a biocompatible polymer, at least one layer of a biocompatible superelastic/shape memory material; and at least one layer of a biocompatible adherent material, and the deployment device comprises a handle section and a deployment section, the deployment section configured to retain the patch for delivery of the patch to the tissue surface.

15. The method of claim 14, wherein retaining the patch to the deployment device comprises using an adhesive to retain the patch to the deployment device.

16. The method of claim 14, wherein retaining the patch to the deployment device comprises applying vacuum to the patch.

18. The method of claim 14, wherein manipulating the deployment device to separate the deployment device from the patch comprises advancing a plunger within the deployment device.

19. The method of claim 14, wherein manipulating the deployment device to separate the deployment device from the patch comprises opening a pair of jaws in the deployment section.

20. The method of claim 14, wherein the patch comprises one or more arms, a base, and barbs extending from the arms, and advancing the deployment device to the tissue surface comprises advancing the deployment device to the tissue surface of the heart.

Applicants submit that the amendment to the independent claims of the instant application overcome this rejection. For example, the independent claims of the instant application now recite that the biocompatible superelastic/shape memory material is in the form of a sheet having an upper side and a lower side and being covered over at least a portion of the upper side and at least a portion of the lower side by the biocompatible material without the use of an adherent material, and the biocompatible superelastic/shape memory material being configured to have a curved configuration in an unconstrained shape if the biocompatible superelastic/shape memory material is configured to be have a superelastic property or to have a curved configuration in a heated, transformed shape if the biocompatible superelastic/shape memory material is configured to have a shape memory property. Applicants respectfully submit that the claims of the instant application are patentably distinct from the claims of the '696 patent and the obviousness-type double patenting rejection should be withdrawn.

In conclusion, Applicants believe all claims are allowable and request a notice of allowance. The Examiner is urged to contact the undersigned should she have any questions. Although no charges are believed due, authorization is given to apply any charges or credits to Deposit Account No. 502923. Applicants claim a small entity status.

Respectfully submitted,

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